510(k) Summary

OCT - 4 2011

Submitter's Name: Toshiba America Medical Systems, Inc.
Address: PO Box 2068, 2441 Michelle Drive Tustin, CA 92781-2068
Contact: Paul Biggins, Director Regulatory Affairs
Telephone No.: (714) 730-5000

Preparation Date: September 30, 2011

Device Proprietary Name: Diagnostic Ultrasound System
Aplio 500 Model TUS-A500 Version 2.0
Aplio 400 Model TUS-A400 Version 2.0
Aplio 300 Model TUS-A300 Version 2.0

Common Name: Diagnostic Ultrasound System

Classification:

- **Regulatory Class: II**
- **Review Category: Tier II**
- Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN
  [Fed. Reg. No.: 892.1550]
- Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO
  [Fed. Reg. No.: 892.1560]
- Diagnostic Ultrasonic Transducer – Product Code: 90-ITX
  [Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:
Toshiba America Medical Systems believes that this device is substantially equivalent to:

- K103645 – Toshiba Diagnostic System Aplio XG SSA-790A v5.2
- K090158 – Toshiba Diagnostic Ultrasound system Aplio Artida SSH-880A v2.0
- K092271 – General Electric LOGIC E.9 Ultrasound System

Device Description:
The Aplio 500/400/300 system is a mobile ultrasound system. It is a Track 3 device that employs a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz. The Aplio 500/400/300 is designed to support a wide range of applications depending on which software is installed. The system can be a dedicated system or a general purpose system.

Intended Use:
The system is intended to be used for the following type of studies; fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular and musculo-skeletal (both conventional and superficial).

Declaration of Conformity:
This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-1 (applicable portion), IEC 60601-1-2 (applicable portion), IEC 60601-1-4 (applicable portion), IEC60601-2-37 (applicable portions), IEC 62304 (applicable portion)

and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.

Testing has been conducted per the following standards:

- IEC 60601-1-1
- IEC 60601-1
- IEC 60601-2-37
- IEC 60601-1-4
- IEC 62304

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

OCT - 4 2011

Re: K110870
Trade/Device Name: Aplio TUS-A500/A400/A300 (v2.0) Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYO, IYN, and ITX
Dated: August 10, 2011
Received: August 11, 2011

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Aplio TUS-A500/A400/A300 (v2.0) Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

PLT-1202S	PST-25BT	PVT-674BT
PLT-1204BT	PST-30BT	PVT-675MV
PLT-1204BX	PVT-375BT	PVT-681MV
PLT-1204MV	PVT-375MV	PLT-712BT
PET-510MB	PVT-382BT	PLT-745BTV
PC-20M	PVT-382MV	PLT-704BT
PC-50M	PVT-661VT	PLT-805AT

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

510(K) Number (if known): K110870

Device Name: Aplio TUS-A500/A400/A300 (v2.0) Diagnostic Ultrasound System

Indications for Use:

The Aplio TUS-A500/A400/A300 (v2.0) Diagnostic Ultrasound System is indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, pediatric, small organs, trans-vaginal, neonatal cephalic, adult cephalic, cardiac, peripheral vascular, transesophageal, and musculo-skeletal (both conventional and superficial).

Prescription Use_____ AND/OR Over-the Counter Use ✓

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110870

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: _____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal	N	N	N	N	N	2	N	N	N		N	5,7
Abdominal	N	N	N	N	N	2,3	N	N	N		N	5,7,12
Intra-operative (Abdominal)	N	N	N		N	2	N	N	N			4,5
Intra-operative (Neuro)												
Laparoscopic												
Pediatric*	N	N	N	N	N	2,3	N	N	N		N	5,7,12
Small Organ (Note 1)	N	N	N		N	2	N	N	N			4,5,6,7,11
Neonatal Cephalic	N	N	N	N	N	3	N	N	N			
Adult Cephalic	N	N	N	N	N	3	N	N	N			
Trans-rectal	N	N	N		N	2	N	N	N		N	4,5,7,11
Trans-vaginal	N	N	N		N	2	N	N	N		N	4,5,7
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**	N	N	N		N	2	N	N	N			4,5,6,7,11
Musculo-skeletal **(Superficial)**	N	N	N		N	2	N	N	N			4,5,6,7,11
Intravascular												
Other (Specify)												
Cardiac Adult	N	N	N	N	N	3	N	N	N	N		4
Cardiac Pediatric	N	N	N	N	N	3	N	N	N	N		4
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	N	N	N	N	N	3	N					4
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N	N	N	2	N	N	N			4,5,6,7,11
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645
Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K110870

Prescription Use Only (Per 21 CRF801.109)

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PLT-1202S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)	N	N	N		N	2	N		N			4,5,11
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	N	N	N		N	2	N		N			4,5,11
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)	N	N	N		N	2	N		N			4,5,11
Musculo-skeletal (**Superficial**)	N	N	N		N	2	N		N			4,5,11
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N		N	2	N		N			4,5,11
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K110870

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PLT-1204BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	N	N	N		N	2	N	N	N			4,5,6,7,11
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**	N	N	N		N	2	N	N	N			4,5,6,7,11
Musculo-skeletal **(Superficial)**	N	N	N		N	2	N	N	N			4,5,6,7,11
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N		N	2	N	N	N			4,5,6,7,11
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

Mary S Patel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110870

Prescription Use Only (Per 21 CRF801.109)

System: Aplio TUS-A500 v2.0
Transducer: PLT-1204BX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	N	N	N		N	2	N	N	N			5,7
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**	N	N	N		N	2	N	N	N			5,7
Musculo-skeletal **(Superficial)**	N	N	N		N	2	N	N	N			5,7
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N		N	2	N	N	N			5,7
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

Mary S Patel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K110870

Prescription Use Only (Per 21 CRF801.109)

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PLT-1204MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	N	N	N		N	2	N	N	N		N	5,7,8,9,10
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**	N	N	N		N	2	N	N	N		N	5,7,8,9,10
Musculo-skeletal **(Superficial)**	N	N	N		N	2	N	N	N		N	5,7,8,9,10
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N		N	2	N	N	N		N	5,7,8,9,10
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K110870

Prescription Use Only (Per 21 CRF801.109)

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PET-510MB

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	N	N	N	N	N	3	N					4,13
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

Mary S Patel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K110870

Prescription Use Only (Per 21 CRF801.109)

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PC-20M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult				N								
Cardiac Pediatric				N								
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel				N								
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110870

Prescription Use Only (Per 21 CRF801.109)

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PC-50M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult				N								
Cardiac Pediatric				N								
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel				N								
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110870

Prescription Use Only (Per 21 CRF801.109)

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PST-25BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal	N	N	N	N	N	3	N	N	N			11
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N	N	N	3	N	N	N			
Small Organ (Specify) (1)												
Neonatal Cephalic	N	N	N	N	N	3	N	N	N			
Adult Cephalic	N	N	N	N	N	3	N	N	N			
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)												
Musculo-skeletal (**Superficial**)												
Intravascular												
Other (Specify)												
Cardiac Adult	N	N	N	N	N	3	N	N	N	N		4,13
Cardiac Pediatric	N	N	N	N	N	3	N	N	N	N		4,13
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

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510K K110870

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PST-30BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal	N	N	N	N	N	3	N	N	N			11
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N	N	N	3	N	N	N			
Small Organ (Specify) (1)												
Neonatal Cephalic	N	N	N	N	N	3	N	N	N			
Adult Cephalic	N	N	N	N	N	3	N	N	N			
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)												
Musculo-skeletal (**Superficial**)												
Intravascular												
Other (Specify)												
Cardiac Adult	N	N	N	N	N	3	N	N	N	N		4,13
Cardiac Pediatric	N	N	N	N	N	3	N	N	N	N		4,13
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

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510K K110870

Prescription Use Only (Per 21 CRF801.109)

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PVT-375BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal	N	N	N		N	2	N	N	N			5, 7
Abdominal	N	N	N		N	2	N	N	N			5, 7,11,12
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N			5, 7,12
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

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510K K110870

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PVT-375MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal	N	N	N		N	2	N	N	N		N	5,7,8,9,10
Abdominal	N	N	N		N	2	N	N	N		N	5,7,8,9,10
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N		N	5,7,8,9,10
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

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510K K110870

Prescription Use Only (Per 21 CRF801.109)

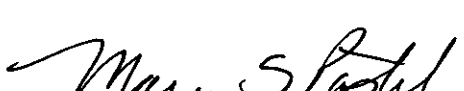
System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PVT-382BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal	N	N	N		N	2	N	N	N			5, 7
Abdominal	N	N	N		N	2	N	N	N			5, 7
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N			5, 7
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)												
Musculo-skeletal (**Superficial**)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT



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510K K110820

Prescription Use Only (Per 21 CRF801.109)

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PVT-382MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal	N	N	N		N	2	N	N	N		N	5, 7,9
Abdominal	N	N	N		N	2	N	N	N		N	5, 7,9
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N		N	5, 7,9
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

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510K K110870

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PVT-661VT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	N	N	N		N	2	N	N	N			4,5,7,11
Trans-vaginal	N	N	N		N	2	N	N	N			4,5,7,11
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)												
Musculo-skeletal (**Superficial**)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

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510K k110870

Prescription Use Only (Per 21 CRF801.109)

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PVT-674BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal	N	N	N		N	2	N	N	N			5,7
Abdominal	N	N	N		N	2	N	N	N			5,7
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N			5,7
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

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510(k) K110870

Prescription Use Only (Per 21 CRF801.109)

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PVT-675MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal	N	N	N		N	2	N	N	N		N	5,7,8,9,10
Abdominal	N	N	N		N	2	N	N	N		N	5,7,8,9,10
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N		N	5,7,8,9,10
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal (**Superficial**)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

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510K K110870

Prescription Use Only (Per 21 CRF801.109)

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PVT-681MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	N	N	N		N	2	N	N	N		N	4,5,7,9,11
Trans-vaginal	N	N	N		N	2	N	N	N		N	4,5,7,9,11
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

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510K K110870

Prescription Use Only (Per 21 CRF801.109)

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PLT-712BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal	N	N	N		N	2	N	N	N			5,7
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N			5,7
Small Organ (Specify) (1)												
Neonatal Cephalic	N	N	N		N	2	N	N	N			5,7
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645
Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

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510K K110870

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PLT-745BTV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal	N	N	N		N	2	N	N	N			5,7
Intra-operative (Abdominal)	N	N	N		N	2	N	N	N			5,7
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645
Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Note 12 Fusion
Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K110870

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PLT-704SBT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	N	N	N		N	2	N	N	N			5,7
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**	N	N	N		N	2	N	N	N			5,7
Musculo-skeletal **(Superficial)**	N	N	N		N	2	N	N	N			5,7
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N		N	2	N	N	N			5.7
Other (Specify)												

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Previous 510(k) of the transducer: K103645
Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110870

System: Aplio TUS-A500/A400/A300 v2.0
Transducer: PLT-805AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	N	N	N		N	2	N	N	N			5,6,7,11
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)	N	N	N		N	2	N	N	N			5,6,7,11
Musculo-skeletal (**Superficial**)	N	N	N		N	2	N	N	N			5,6,7,11
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N		N	2	N	N	N			5,6,7,11
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
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